

ADDENDUM REGARDING CERTAIN SUMMARY EXHIBITS

1. In the course of preparing for my testimony in this matter, I have prepared several summary exhibits. These exhibits summarize data that are too voluminous to present to the Court in any other convenient way. Some of them also combine data from multiple sources—many of them voluminous—in order to illustrate one or another point in my testimony. I set forth below an explanation of each of these exhibits.

Exhibits 2918 & 2947

2. Exhibit 2918 is titled "Comparison of Estimated Monthly Medicare Reimbursements for Albuterol Sulfate 0.5% Solution: 2004 v. 2005, 30-Day Supply of 225mg."

3. Exhibit 2918 sets out the reimbursement rates for two HCPCS codes relating to the reimbursement for 0.5% albuterol sulfate.

4. Column (c) of the chart uses the average quarterly payment limit drawn from the CMS files and multiplies it by the dosage for a 30-day supply for 2005. For 2004, the allowance from the DMERC schedule is used, multiplied by the lower bound of the dosage range. These payment limit files are from the CMS web site.

5. Because the CMS ASP Drug Pricing Files are maintained as a database, the data contained in them would be cumbersome and difficult for the Court to review in their original format. I have therefore set out the relevant data from the CMS ASP Drug Pricing Files in this more convenient format.

6. Column (d) of the chart shows dispensing fees extracted from the Federal Register.

7. Column (e) represents the result of the calculation I performed determining the total reimbursement for the J-Codes in this chart by summing the reimbursement amount and the dispensing fee.

8. Finally, I have also identified a CMS publication titled “Medicare Region B DMERC, HCPCS Update-2005.” This public record is not summarized in Exhibit 2918. Instead, I used this report to confirm the J-Codes associated with albuterol sulfate 0.5% solution.

9. Exhibit 2947 is a graphical representation of the data in Exhibit 2918.

Exhibits 2919, 2946, 2949 & 2950

10. Exhibit 2919 is titled "Last Recorded Medispan AWP of Albuterol Sulfate 0.083%."

11. Exhibit 2919 is a chart that summarizes data from the “Comprehensive Price History File” (“Medispan”). Medispan is a provider of drug pricing information that is generally used in the pharmaceutical industry. The database is in an electronic format, and so I have extracted and summarized the relevant data for the Court. In this case, I have compiled the AWP that appear in the Medispan file for National Drug Codes (“NDCs”) associated with albuterol sulfate 0.083% solution. Unit AWP are evaluated as of June 30th of each year based on the latest AWP posted in Medispan before that date.

12. There are a number of sources identified at the bottom of Exhibit 2919. These sources are not summarized in this chart. Instead, these sources were used to match the NDCs to their respective manufacturers.

13. Exhibit 2946 is a graph depicting a subset of the data that appear in Exhibit 2919.

14. Exhibit 2949 is a chart that repeats the data from the fourth column of the first page of Exhibit 2919, rounded to the nearest cent and re-sorted.

15. Exhibit 2950 is a graphical representation of the AWP associated with Warrick's 0.083% albuterol sulfate as recorded in Exhibit 2919.

Exhibits 2920 & 2945

16. Exhibit 2920 is titled "Last Recorded Medispan AWP of Albuterol Sulfate 0.5%." In this chart, I have accumulated the unit AWP that appear in the Medispan data for NDCs associated with albuterol sulfate 0.5% solution. The unit AWP are evaluated as of June 30th of each year based on the latest AWP posted prior to that date.

17. There are a number of sources identified at the bottom of Exhibit 2920. These sources are not summarized in this chart. Instead, these sources were used to match the NDCs to their respective manufacturers.

18. Exhibit 2945 is a graphical depiction of a subset of the data in Exhibit 2920.

Exhibits 2921 & 2952

19. Exhibit 2921 is a chart I prepared titled "Warrick and Median AWP, FULs and Median VA Prices for Generic Albuterol Sulfate 0.083% Products, 1991-2004."

20. The Warrick and median AWP values that appear in Exhibit 2921 are a subset of the data in 2919. The FUL data listed in 2921 are extracted from the Medispan file, evaluated as of June 30th.

21. The last line lists the VA Median Price, adjusted to be a per-milliliter price based on OIG conversion methodology and as reported in a 2002 OIG report titled "Excessive Medicare Reimbursement for Albuterol."

22. Exhibit 2952 is a graphical representation of the data in column (j) of Exhibit 2921, rounded to the nearest cent.

Exhibit 2922A

23. Exhibit 2922A is titled "Summary of Relative AWP Analysis for Warrick's Albuterol NDCs Analyzed by Dr. Hartman in the MDL, 1991-2004."

24. Exhibit 2922A summarizes data from the Medispan file for the Warrick albuterol NDCs identified by Dr. Hartman in his December 15, 2005 declaration, as well as the NDCs of non-accused competitor products that also appear in the Medispan data.

25. To prepare this chart, I counted the number of accused Warrick albuterol NDCs for which there was a reported AWP in the Medispan data by year and entered that total in line (b). Line (c) is the number of NDCs for which the AWP of a non-accused product with the same product description is higher than Warrick's AWP. Line (d) is the number of NDCs for which the AWP data for non-accused competitors with the same product description exist. Line (e) is the number of NDCs that do not fall into any of the other categories. Lines (f) through (j) represent a simple arithmetical calculation to express the information in lines (c) through (e) as a percentage.

Exhibit 2923A

26. Exhibit 2923A is titled "Summary of Relative AWP Analysis for Intron-A NDCs Analyzed by Dr. Hartman in the MDL, 1991 - 2004."

27. Exhibit 2923A summarizes data from the Medispan file for the Intron-A NDCs identified by Dr. Hartman in his December 15, 2005 declaration as well as the NDCs of non-accused competitor products that also appear in the Medispan data.

28. To create this chart, I counted the number of accused Intron-A NDCs for which there was a reported AWP in the Medispan data by year and entered that total in line (b). Line (c) is the number of NDCs for which the AWP changed and there is a non-accused competing product with a similar product description that grew faster. Line (d) is the number of NDCs for which the AWP changed and there is a non-accused competing product that grew faster. Line (e) is the number of NDCs for which the AWP did not change and there is a competing non-accused

product that did change. Line (f) is the number of NDCs for which the AWP did not change and there are no non-accused competing products that did change. Line (g) is the number of NDCs for which the AWP of a non-accused competing product is higher than Schering's AWP. Line (h) is the number of NDCs for which the AWP of a non-accused competing product is higher than Schering's AWP. Line (i) is the number of NDCs for which AWP data for non-accused competitors exist. Line (j) is the number of NDCs that do not fall into any of the other categories.

29. Lines (k) through (s) represent a simple arithmetical calculation to express the information in lines (c) through (j) as a percentage.

Exhibit 2925A

30. Exhibit 2925A is titled "Summary of Relative AWP Analysis for Proventil NDCs Analyzed by Dr. Hartman in the MDL, 1991 - 2004."

31. Exhibit 2925A summarizes data from the Medispan file for the Schering NDCs identified by Dr. Hartman in his December 15, 2005 declaration as well as the NDCs of non-accused competitor products that also appear in the Medispan data.

32. To prepare this chart, I counted the number of accused Proventil NDCs for which there was a reported AWP in the Medispan data by year and entered that total in line (b). Line (c) is the number of NDCs for which the AWP changed and there is a non-accused competing product with a similar product description that grew faster. Line (d) is the number of NDCs for which the AWP changed and there is a non-accused competing product that grew faster. Line (e) is the number of NDCs for which the AWP did not change and there is a non-accused competing product that did change. Line (f) is the number of NDCs for which the AWP did not change and there are no non-accused competing products that did change. Line (g) is the number of NDCs

for which the AWP of a non-accused competing product is higher than Schering's AWP. Line (h) is the number of NDCs for which the AWP of a non-accused competing product is higher than Schering's AWP. Line (i) is the number of NDCs for which AWP data for non-accused competitors exist. Line (j) is the number of NDCs that do not fall into any of the other categories.

33. Lines (k) through (s) represent a simple arithmetical calculation to express the information in lines (c) through (j) as a percentage.

Exhibit 2926A

34. Exhibit 2926A is titled "Summary of Relative AWP Analysis for Temodar NDCs Analyzed by Dr. Hartman in the MDL, 1991 - 2004."

35. Exhibit 2926A summarizes data from the Medispan file for the Schering NDCs identified by Dr. Hartman in his December 15, 2005 declaration as well as the NDCs of non-accused competitor products that also appear in the Medispan data.

36. To create this chart, I counted the number of accused Temodar NDCs for which there was a reported AWP in the Medispan data by year and entered that total in line (b). Line (c) is the number of NDCs for which the AWP changed and there is a non-accused competing product with a similar product description that grew faster. Line (d) is the number of NDCs for which the AWP changed and there is a non-accused competing product that grew faster. Line (e) is the number of NDCs for which the AWP did not change and there is a non-accused competing product that did change. Line (f) is the number of NDCs for which the AWP did not change and there are no non-accused competing products that did change. Line (g) is the number of NDCs for which the AWP of a non-accused competing product is higher than Schering's AWP. Line (h) is the number of NDCs for which the AWP of a non-accused competing product is higher

than Schering's AWP. Line (i) is the number of NDCs for which AWP data for non-accused competitors exist. Line (j) is the number of NDCs that do not fall into any of the other categories.

37. Lines (k) through (s) represent a simple arithmetical calculation to express the information in lines (c) through (j) as a percentage.

Exhibits 2927 & 2951

38. Exhibit 2927 is titled "Unit AWP's and Market Shares by Manufacturer for Albuterol Sulfate 0.083% Products, 2000-2004."

39. Columns (a) through (e) of this chart summarize, by year, the market shares for various manufacturers' albuterol sulfate 0.083% products, as calculated from sales data reported by IMS. IMS is a commercially-available service that provides market data regarding pharmaceuticals. The IMS data are generally used and relied upon by participants in the pharmaceutical industry. To assist the Court in reviewing these data, counsel asked me to prepare these figures. I have therefore extracted portions of these data.

40. Columns (f) through (j) summarize the AWP's listed in Medispan based on the latest posting as of June 30th for each manufacturer's albuterol sulfate 0.083% NDCs.

41. Exhibit 2951 is a graphical representation of a subset of the data in Exhibit 2927.

Exhibit 2928

42. Exhibit 2928 is titled "Unit AWP's and Market Shares by Manufacturer for Albuterol Sulfate 0.5% Products, 2000-2004."

43. Columns (a) through (e) of this chart summarize, by year, the market shares for various manufacturers' albuterol sulfate 0.5% products, as calculated from sales data reported by IMS.

44. Columns (f) through (j) summarize the AWP's listed in Medispan based on the latest posting as of June 30th for each manufacturer's albuterol sulfate 0.5% NDCs.

Exhibit 2929

45. Exhibit 2929 is titled "Percent Change in Schering Intron-A Unit AWP's Between Consecutive Years, 1991 - 2005."

46. The chart in Exhibit 2929 summarizes a simple series of calculations I performed on AWP data appearing in the Medispan database. For each NDC, I compared the AWP on June 30th of a given year to its AWP on that date in the previous year. For those years in which an AWP associated with a particular NDC changed, I performed a simple calculation to determine the percentage by which that AWP had changed from the previous year.

47. The other materials listed at the bottom of Exhibit 2929 are materials produced by the Plaintiffs in this case, which I used to determine the NDCs for which to gather data and perform this calculation.

Exhibits 2930 & 2953

48. Exhibit 2930 is titled "Unit AWP's for Intron-A, Adjusted for Concentration, 1986-2004."

49. Exhibit 2930 is a summary of series of simple calculations I performed on data obtained from the Medispan database.

50. For each Intron-A NDC analyzed by Dr. Hartman in the MDL, I divided the AWP posted in Medispan by the concentration of the drug at issue. The results of that series of calculations are set out in the chart.

51. The other materials listed at the bottom of Exhibit 2930 are materials that were used to determine which NDCs were analyzed by the Dr. Hartman to ensure that the correct data were extracted from the Medispan database and for information on concentration.

52. Exhibit 2953 is a graphical representation of the data in Exhibit 2930. The only modification is that the NDCs for “physician-administered drugs” and “self-administered drugs”, according to the May 25, 2006 Declaration of Jack Micali, are charted separately.

Exhibit 2931

53. Exhibit 2931 is titled "Medicare Reimbursement Limits as a Percent of Average Wholesale Price by HCPCS Code."

54. Exhibit 2931 is compiled from data in different sources published on the CMS website: the 2004 MMA Drug Payment Limits; and the Medicare Claims Processing Manual.

55. Both of the sources described above are public records of CMS's activities in setting reimbursement rates for Medicare. The summary here avoids duplication as the lists have substantial overlap.

Exhibits 2933, 2956 and 2957.

56. Exhibit 2933 is titled "Distribution of Sales by Percentage of WAC Paid by Schering Customers, Proventil."

57. To prepare Exhibit 2933, I compared the average sales price by customer calculated from sales data reported in Schering's Direct Sales and Chargeback Invoice data to the WAC (calculated using Medispan AWP data as AWP/1.2 and AWP/1.25 after January 1, 2002) for the period 1991 to 2004, and allocated these sales based on the percentage ranges of WAC that the “ASP” represented. The Schering Direct Sales and Chargeback Invoice are Schering business records provided to me for purposes of this litigation. Because these records are voluminous and maintained in a large database, it would be impractical to present them to the Court in their original format.

58. Exhibits 2956 and 2957 are graphical representations of the data in 2933, showing the range of discounted prices from at or above list price to 80 percent of list price and below.

Exhibits 2934, 2958 and 2959

59. Exhibit 2934 is titled "Distribution of Sales by Percentage of WAC Paid by Schering Customers, Intron-A."

60. To prepare Exhibit 2934, I compared the average sales price by customer calculated from sales data reported in Schering's Direct Sales and Chargeback Invoice data to the WAC (calculated using Medispan AWP data as AWP/1.2 and AWP/1.25 after January 1, 2002) for the period 1991 to 2004, and allocated these sales based on the percentage ranges of WAC that the "ASP" represented.

61. Exhibits 2958 and 2959 are graphical representations of the data in 2934, showing the range of discounted prices from at or above list price to 80 percent of list price and below.

Exhibits 2935, 2954 & 2955

62. Exhibit 2935 is titled "Distribution of Sales by Percentage of WAC Paid by Schering Customers, Temodar."

63. To prepare Exhibit 2935, I compared the average sales price by customer calculated from sales data reported in Schering's Direct Sales and Chargeback Invoice data to the WAC (calculated using Medispan AWP data as AWP/1.2 and AWP/1.25 after January 1, 2002) for the period 1991 to 2004, and allocated these sales based on the percentage range of WAC that the "ASP" represented.

64. Exhibits 2954 and 2955 are graphical representations of the data in Exhibit 2935, showing the range of discounted prices from at or above list price to 80 percent of list price and below.

Exhibits 2936, 2943 & 2944

65. Exhibit 2936 is titled "Comparative Breakdown of Payment Source for Proventil and Albuterol Sulfate 0.083% and 0.5% Products Using NDTI Data, October 1997-2004."

66. Exhibit 2936 summarizes a calculation I performed using data from IMS's National Disease and Therapeutic Index ("NDTI"). The NDTI is a commercial database available to participants in the pharmaceutical industry. Because the NDTI is maintained as a database with information on thousands of drugs it would be impractical to present the entire database to the Court.

67. I prepared Exhibit 2936 by extracting from the NDTI data the number of reimbursements appearing in the data for each type of payor for Proventil and albuterol, based on the drug description. I then calculated shares and adjusted the share for Medicare-related payors to account for the fact that some payments were apparently made by unknown or unspecified payers by applying the equation shown in bold at the bottom of the chart and further explained in footnote 5.

68. Exhibit 2943 is a graphical representation of the data in columns (a) and (b) in Exhibit 2936.

69. Exhibit 2944 is a graphical representation of the data in columns (c) and (d) in Exhibit 2936.

Exhibits 2938 & 2948

70. Exhibit 2938 is titled "Implied Unit ASPs and Dollar Spreads for Albuterol 59930150006 and Intron-A 00085053901 Based on Dr. Hartman's Declaration of December 15, 2005".

71. I prepared Exhibit 2938 by extracting data from Medispan associated with the NDCs 59930150006 and 00085053901 and then performing some simple calculations.

72. Column (a) represents the package AWP reported in Medispan for the two NDCs. Column (b) represents the unit AWP. By dividing the data in column (a) by the data in column (b), we obtained the implied pack size, which I have entered in column (c). Columns (d) and (e), respectively, are the "spreads" calculated by Dr. Hartman and his reported Package AWP, both of which are from his Liability Backup for the December 15, 2005 Declaration. By dividing Dr. Hartman's ASP figure by the number of units per package that I have entered in column (c), Dr. Hartman's Package ASP is converted to an implied unit ASP. I have recorded that figure in column (f). Finally, Dr. Hartman's "spreads" are multiplied by his Package ASPs, yielding the "spread" between AWP and ASP in dollars, then divided by the Implied Package Size, to get the Implied Unit Dollar Spread. I have recorded the results of that calculation in column (g).

73. Exhibit 2948 is a graphical representation of the data in Exhibit 2938.

Exhibit 2939 & 2960

74. Exhibit 2939 is titled "NDCs/Years Where Dr. Hartman Finds Liability for Branded Products in Class 3" and includes four charts, subtitled "Dr. Hartman's AWP", "'ASPs' for Sales to Full Line Wholesalers", "'Spreads' Based on 'ASPs' for Sales to Full Line Wholesalers and Dr. Hartman's AWP", and "Instances Where 'Spreads' Exceed 30 Percent."

- a) The first chart, "Dr. Hartman's AWP", provides the AWP from Dr. Hartman's Attachment G.4.b to his direct testimony for those drugs for which Dr. Hartman finds liability for Class 3 as reported in Attachment I.4 to his direct testimony.
- b) The second chart, "'ASPs' for Sales to Full Line Wholesalers", summarizes the "ASPs" calculated from the Schering sales data for sales of the drugs identified in Dr. Hartman's testimony to full line wholesalers, limited to those drugs for which Dr. Hartman finds liability for Class 3 as reported in Attachment I.4 to his direct testimony.

- c) The third chart, "'Spreads' Based on 'ASPs' for Sales to Full Line Wholesalers and Dr. Hartman's AWP's" summarizes a series of calculations in which I took the full line wholesaler "ASPs" reported in the second chart and used Dr. Hartman's AWP's (the first chart) to calculate "spreads" for sales to full line wholesalers.
- d) The fourth chart, "Instances Where 'Spreads' Exceed 30 Percent" identifies the instances in the third chart where the "spread" for full line wholesalers is greater than 30 percent.

75. Exhibit 2960 is a graphical representation of the fourth chart in Exhibit 2939.

Exhibit 2940

76. Exhibit 2940 is titled "Distribution of Sales by Percentage of WAC Paid by Schering Customers in the 'Governmental Buyers' Class of Trade, Intron-A, 1991-2004."

77. To prepare Exhibit 2940, I compared the average sales price by customer calculated from sales data reported in Schering's Direct Sales and Chargeback Invoice data to the WAC (calculated using Medispan AWP data as AWP/1.2 and AWP/1.25 after January 1, 2002) for the Intron-A NDCs analyzed by Dr. Hartman. When performing this comparison, I limited the Schering Sales Data to those records involving classes of trade representing governmental buyers.

78. The data in column (c) sums the sales for customers whose "ASP" is a particular percentage of WAC. Column (d) was created by dividing the number in column (c) by the sum of column (c).

Exhibit 2941

79. Exhibit 2941 is titled "Distribution of Sales by Percentage of WAC Paid by Schering Customers in the 'Governmental Buyers' Class of Trade, Proventil, 1991-2004."

80. To prepare Exhibit 2941 I compared the average sales price by customer calculated from sales data reported in Schering's Direct Sales and Chargeback Invoice data to the WAC (calculated using Medispan AWP data as AWP/1.2 and AWP/1.25 after January 1, 2002) for the Proventil NDCs either analyzed by Dr. Hartman or accused in the Plaintiffs' Complaint . When performing this comparison, I limited the Schering Sales Data to those records involving classes of trade for governmental buyers.

81. The data in column (c) sums the sales for customers whose "ASP" is a particular percentage of WAC. Column (d) was created by dividing the number in column (c) by the sum of column (c).

Exhibit 2942

82. Exhibit 2942 is titled "Distribution of Sales by Percentage of WAC Paid by Schering Customers in the 'Governmental Buyers' Class of Trade, Temodar, 1991-2004."

83. To prepare Exhibit 2942, I compared the average sales price by customer calculated from sales data reported in Schering's Direct Sales and Chargeback Invoice data to the WAC (calculated using Medispan AWP data as AWP/1.2 and AWP/1.25 after January 1, 2002) for each Temodar NDC analyzed by Dr. Hartman. When performing this comparison, I limited the Schering Sales Data to those records involving classes of trade for governmental buyers.

84. The data in column (c) sums the sales for customers whose "ASP" is a particular percentage of WAC. Column (d) was created by dividing the number in column (c) by the sum of column (c).